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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/394,204	09/10/99	STERN	D 52209-A-PCT-

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EXAMINER	
HAYES,R	
ART UNIT	**PAPER NUMBER**
1647	7

DATE MAILED: 09/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/394,204	Stern et al
Examiner	**Art Unit**
Robert C. Hayes, Ph.D.	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-25* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). ___
18) ☐ Interview Summary (PTO-413) Paper No(s). ___
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: ___

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-5, drawn to purified ERAB polypeptides, classified in Class 530, subclass 350.

   II. Claims 6-15, drawn to isolated nucleic acids that encode ERAB polypeptides, as well as vectors and host cells comprising such, classified in Class 435, subclass 320.1.

   III. Claims 16-17, drawn to antibodies to ERAB polypeptides, classified in Class 530, subclass 387.1.

   IV. Claims 18-19, drawn to transgenic non-human mammals, classified in Class 800, subclass 2.

   V. Claims 20-21, drawn to methods of testing/evaluating agents to inhibit binding of ERAB to amyloid-beta peptide, classified in Class 435, subclass 7.1.

   VI. Claim 22, drawn to a method for treating neurodegeneration with agents that inhibit binding of ERAB to amyloid-beta peptide, and pharmaceutical compositions thereof, classified in Class 424, subclass 130.1+.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products appear to constitute patently distinct inventions for the following reason:

Groups I-IV are directed to products that are physically and functionally distinct that include polypeptides, polynucleotides, antibodies and transgenic animals. All of these products can be prepared by different processes, such as though chemical synthesis or isolation from natural sources using various isolation/purification procedures. For example, the proteins of Group I and antibodies of Group III are fundamentally different molecules than the polynucleotide molecules of Group II, which in turn can be used to clone the protein, used in gene therapy, or used to identify cells expressing the protein. Although the antibodies of Group III can be used in isolating the protein of Group I, the antibodies of Group III can be generated by immunizing animals with a small synthetic portion of the full length protein, and can be used diagnostically in other ways, such as in affinity chromatography or in immunoassays, or as therapeutic agents themselves. In contrast, the proteins of Group I can be utilized in making the antibodies of Group III, but not vice versa. The transgenic animals of Group IV can be used to study the effects of expression and activity of the recombinant DNA molecules of Group II, but do not necessarily contain the same isolated DNA molecules/vector sequences of Group II. Moreover, the transgenic animals of Group VII are not required in the products of Groups I-III, and vice versa. Additionally, neither the proteins of Group I nor the antibodies of Group III

require the vectors and host cells of Group II, and vice versa. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the polypeptide molecules of Group I can be used to generate antibodies. In contrast, the method of testing for agents that inhibit binding of ERAB with amyloid-beta, require amyloid-beta peptide, additional "binding" molecules, as well as appropriate labeling protocols, etc., none of which are required in Group I. Additionally, the methods of Group V does not require the products of Groups II-IV, and vice versa.

Although there are no provisions under the section for "Relation of Inventions" in MPEP § 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Groups V-VI are directed to methods of treating neurodegeneration or directed toward methods of detecting new compounds that inhibit binding of ERAB with amyloid-beta peptide. Each of these methods require physically and functionally distinct elements. For example, the method of Group V requires use of the proteins of Group I, which are entirely different

components than those compounds that may inhibit binding of ERAB with amyloid-beta. The treatment method of Group V further requires administration protocols and patients with a neuro-degenerative disease, which are not required in the detection method of Group VI. Alternatively, the detection of Group VI requires labeling protocols, and different products not required in the treatment methods of Group V, and vice versa. These inventions are, therefore, patentably distinct, since one is not required for the other.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
September 26, 2001

GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600